



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/291,894 | 04/13/99 | COLLINS | P 17634-000520 |

020350 HM22/1220
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER

BRUMBACK, B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1642 | // |

DATE MAILED: 12/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/291,894

Applicant(s)

Collins et al.

Examiner

Brenda Brumback

Group Art Unit

1642



☒ Responsive to communication(s) filed on Nov 14, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-35 and 46-65 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-35 and 46-65 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

DETAILED ACTION

1. This action is responsive to the amendment filed 11/14/2000. Claims 36-45 were canceled. Claims 1-3, 52-54, 64, and 65 were amended. Claims 1-35 and 46-65 are pending.
2. Pursuant to the interviews of October 2, 2000 and November 7, 2000 and applicant's arguments filed 11/14/2000, the previous restriction requirement is withdrawn in view of the new restriction requirement with election of species which follows:

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-30, 35, and 46-65, drawn to chimeric human respiratory syncytial virus (RSV) and isolated polynucleotides comprising chimeric human RSV genomes, classified in class 424, subclass 211.1 and in class 536, subclass 23.72.
 - II. Claims 1, 22, and 31-33, drawn to chimeric RSV / parainfluenza virus, classified in class 424, subclass 199.1.
 - III. Claims 1 and 34, drawn to chimeric human and bovine or murine RSV, classified in class 424, subclass 202.1.

It is noted that claims 1 and 22 appear in more than one group. These claims will be examined with the elected group to the extent that they read on that group.

Art Unit: 1642

4. The inventions are distinct, each from the other because of the following reasons:

The viruses of Groups I-III have different structures and different immunological properties. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Claims 1-30, 35, and 46-65 are generic to a plurality of disclosed patentably distinct species comprising the following:

Chimeric RSV with an NS1 heterologous gene,
Chimeric RSV with an NS2 heterologous gene,
Chimeric RSV with an N heterologous gene,
Chimeric RSV with a P heterologous gene,
Chimeric RSV with an M heterologous gene,
Chimeric RSV with an SH heterologous gene,
Chimeric RSV with an M2 (ORF1) heterologous gene,
Chimeric RSV with an M2 (ORF2) heterologous gene,
Chimeric RSV with an L heterologous gene,
Chimeric RSV with an F heterologous gene,
Chimeric RSV with a G heterologous gene,

Art Unit: 1642

Chimeric RSV with one or more attenuating mutations present within mutant RSV strain
cpts RSV 248,

Chimeric RSV with one or more attenuating mutations present within mutant RSV strain
cpts RSV 248/404,

Chimeric RSV with one or more attenuating mutations present within mutant RSV strain
cpts RSV 248/955,

Chimeric RSV with one or more attenuating mutations present within mutant RSV strain
cpts RSV 530,

Chimeric RSV with one or more attenuating mutations present within mutant RSV strain
cpts RSV 530/1009,

Chimeric RSV with one or more attenuating mutations present within mutant RSV strain
cpts RSV 530/1030,

Chimeric RSV with one or more attenuating mutations present within mutant RSV strain
RSV B-1 *cp*52/2B5, and

Chimeric RSV with one or more attenuating mutations present within mutant RSV strain
RSV B-1 *cp*-23,

Chimeric RSV with a point mutation specifying a temperature-sensitive amino acid
substitution at Phe₅₂₁,

Chimeric RSV with a point mutation specifying a temperature-sensitive amino acid
substitution at GLN₈₃₁,

Art Unit: 1642

Chimeric RSV with a point mutation specifying a temperature-sensitive amino acid substitution at Met₁₁₆₉,

Chimeric RSV with a point mutation specifying a temperature-sensitive amino acid substitution at Tyr₁₃₂₁,

Chimeric RSV with a nucleotide substitution in the gene-start sequence of gene M2,

Chimeric RSV with a mutation from cold-passaged attenuated RSV at Val₂₆₇ of the N gene,

Chimeric RSV with a mutation from cold-passaged attenuated RSV at Glu₂₁₈ or Thr₅₂₃ of the F gene,

Chimeric RSV with a mutation from cold-passaged attenuated RSV at Cys₃₁₉ or His₁₆₉₀ of the polymerase L gene,

Chimeric RSV with a deletion of the SH gene,

Chimeric RSV further comprising a nucleotide modification specifying a phenotypic change in growth characteristics,

Chimeric RSV further comprising a nucleotide modification specifying a phenotypic change in attenuation,

Chimeric RSV further comprising a nucleotide modification specifying a phenotypic change in temperature sensitivity,

Chimeric RSV further comprising a nucleotide modification specifying a phenotypic change in cold-adaptation,

Art Unit: 1642

Chimeric RSV further comprising a nucleotide modification specifying a phenotypic change in plaque size,

Chimeric RSV further comprising a nucleotide modification specifying a phenotypic change in host-range restriction,

Chimeric RSV further comprising a nucleotide modification specifying a phenotypic change in immunogenicity,

Chimeric RSV wherein the genome or antigenome is modified to encode a cytokine,

Chimeric RSV wherein the genome or antigenome is modified to encode a T-helper epitope,

Chimeric RSV wherein the genome or antigenome is modified to encode a restriction site marker, and

Chimeric RSV wherein the genome or antigenome is modified to encode a protein of a microbial pathogen.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

Art Unit: 1642

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a

Application/Control Number: 09/291,894


Page 8

Art Unit: 1642

Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

December 19, 2000


Brenda Brumback,
Patent Examiner